Food and Drug Administration, HHS

- (c) The expected usage for the product if known to the manufacturer;
- (d) A description of the defect in the product or the manner in which the product fails to comply with an applicable Federal standard;
- (e) An evaluation of the hazards reasonably related to defect or the failure to comply with the Federal standard;
- (f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the Federal standard:
- (g) The date and circumstances under which the defect was discovered; and
- (h) The identification of any trade secret information which the manufacturer desires kept confidential.

§ 1003.21 Notification by the manufacturer to affected persons.

- (a) The notification to the persons specified in §1003.10(b) shall be in writing and, in addition to other relevant information which the Secretary may require, shall include:
- (1) The information prescribed by §1003.20 (a), (d), and instructions with respect to the use of the product pending the correction of the defect;
- (2) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply; and
 - (3) The following statement:

The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, the Secretary has approved a plan for the repair, replacement or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

- (b) The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this section.
- (1) No. 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.

(2) The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle 3¾ inches wide and 2¼ inches high:

IMPORTANT—ELECTRONIC PRODUCT RADIATION
WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36-point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in 36-point Gothic Condensed type.

- (3) Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for mailings other than those required by this part.
 - (c) The notification shall be sent:
- (1) By certified mail to purchasers of the product and to subsequent transferees.
- (2) By certified mail or other more expeditious means to dealers and distributors.
- (d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

- (a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.
- (b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.